

Complete Summary

GUIDELINE TITLE

Evaluation and treatment of the human immunodeficiency virus-1--exposed infant.

BIBLIOGRAPHIC SOURCE(S)

King SM. Evaluation and treatment of the human immunodeficiency virus-1--exposed infant. Pediatrics 2004 Aug; 114(2):497-505. [79 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Human immunodeficiency virus-1(HIV-1)

GUIDELINE CATEGORY

Counseling
Evaluation

Management
Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To provide recommendations to the pediatrician in the prevention of mother-to-child transmission of human immunodeficiency virus-1 (HIV-1)
- To provide recommendations to the pediatrician for the care of HIV-1 exposed infants

TARGET POPULATION

- Pregnant women identified as having human immunodeficiency virus-1 (HIV-1)
- Infants exposed to or infected with HIV-1

INTERVENTIONS AND PRACTICES CONSIDERED

1. Identification of maternal human immunodeficiency virus-1 (HIV-1)
2. HIV-1 testing of the mother or infant with maternal consent, using screening tests: "expedited" HIV-1 enzyme immunoassay (EIA) or rapid testing kits
3. Confirmation of positive screening test with standard HIV-1 testing
4. Prevention measures during pregnancy, labor, and postnatal period with antiretroviral prophylaxis (zidovudine [ZDV]; nevirapine* [NVP]; lamivudine [3TC]) as indicated
5. Assessment at birth for maternal coinfections and follow-up diagnostic testing and treatment of infants based on maternal findings
6. Prevention of secondary opportunistic infections, including Pneumocystis pneumonia [PCP] prophylaxis (trimethoprim-sulfamethoxazole; dapsone; pentamidine; atovaquone) as indicated
7. Immunizations and tuberculosis (TB) screening of infants
8. Monitoring for toxicity from exposure to antiretroviral drugs
9. After birth, ongoing virologic testing for HIV-1 in HIV-1-exposed infant
10. Counseling to parents and caregivers of HIV-1 exposed infants regarding course of HIV-1 illness, infection-control measures (e.g., avoidance of HIV-1 transmission through breastfeeding), care of the infant, diagnostic tests, and potential drug toxicity
11. Family testing of father and siblings

*Note from the National Guideline Clearinghouse: On January 19, 2005, the U.S. Food and Drug Administration (FDA) issued a public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine. The Indications and Usage section now recommends against starting nevirapine treatment in women with CD4+cell counts greater than 250 cells/mm³ unless benefits clearly outweigh risks. This recommendation is based on a higher observed risk of serious liver toxicity in patients with higher CD4 cell counts prior to initiation of therapy. See the [FDA Web site](#) for more information.

MAJOR OUTCOMES CONSIDERED

- Risk and rate of mother-to-child transmission of perinatal human immunodeficiency virus type 1 (HIV-1) infection
- Congenital and perinatal infections associated with HIV-1 infection, such as Pneumocystis pneumonia and tuberculosis
- Sensitivity and specificity of screening and diagnostic tests used to detect HIV-1 infection
- Short and long-term toxicities of antiretroviral exposure

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

1. Whenever possible, maternal human immunodeficiency virus-1 (HIV-1) infection should be identified before or during pregnancy, because this allows for earlier initiation of care for the mother and for more effective interventions to prevent perinatal transmission.
2. If the maternal HIV-1 infection status is unknown at the time of the infant's birth, then HIV-1 testing of the mother or the infant is recommended with maternal consent and with results available within 24 hours of birth. The expedited enzyme immunoassay (EIA) and rapid HIV-1 test are screening tests that may be used in this setting.
3. If the test result for HIV-1 is positive, prophylactic antiretroviral therapy should be started promptly in the infant and confirmatory HIV-1 testing should be performed.
4. HIV-1-infected mothers should not breastfeed their infants and should be educated about safe alternatives (Read, 2003)
5. Maternal health information should be reviewed to determine if the HIV-1-exposed infant may have been exposed to maternal coinfections including tuberculosis (TB), syphilis, toxoplasmosis, hepatitis B or C, cytomegalovirus, and herpes simplex virus. Diagnostic testing and treatment of the infant are based on maternal findings.
6. Pediatricians should provide counseling to parents and caregivers of HIV-1-exposed infants about HIV-1 infection, including anticipatory guidance on the course of illness, infection-control measures, care of the infant, diagnostic tests, and potential drug toxicity.
7. All HIV-1-exposed infants should undergo virologic testing for HIV-1 at birth, at 4 to 7 weeks of age, and again at 8 to 16 weeks of age to reasonably exclude HIV-1 infection as early as possible. If any test result is positive, the

- test should be repeated immediately for confirmation. If all test results are negative, the infant should have serologic testing repeated at 12 months of age or older to document disappearance of the HIV-1 antibody, which definitively excludes HIV-1 infection.
8. All infants exposed to antiretroviral agents in utero or as infants should be monitored for short and long-term drug toxicity.
 9. Prophylaxis for *Pneumocystis pneumonia* (PCP) should be started at 4 to 6 weeks of age in HIV-1–exposed infants in whom infection has not been excluded. PCP prophylaxis may be discontinued when HIV-1 infection has been reasonably excluded.
 10. Immunizations and TB screening should be provided for HIV-1–exposed infants in accordance with national guidelines. In the United States, immunization guidelines are established by the AAP, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, and the American Academy of Family Physicians; in Canada, guidelines are established by the National Advisory Committee for Immunizations.
 11. HIV-1 testing should be offered and recommended to family members.
 12. The practitioner providing care for the HIV-1–exposed or HIV-1–infected infant should consult with a pediatric HIV-1 specialist and, if the HIV-1–infected mother is an adolescent, also consult with a practitioner familiar with the care of adolescents.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting each recommendation is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Effective prevention of transmission from mother-to-child of human immunodeficiency virus-1 (HIV-1)
- Effective care of the HIV-1 exposed infant
- Early identification of the HIV-1 infected infant
- Prevention of congenital and perinatal infections associated with HIV-1 infection, such as *Pneumocystis pneumonia* and tuberculosis

POTENTIAL HARMS

- Some studies suggest that combination antiretroviral therapy during pregnancy increases the risk of preterm birth and other adverse outcomes of pregnancy.
- The most common short-term adverse consequence with zidovudine (ZDV) prophylaxis is anemia.
- Human immunodeficiency virus-1 (HIV-1) virologic testing may result in false-positive or false-negative results.

CONTRAINDICATIONS

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Bacillus Calmette-Guerin (BCG) vaccine is contraindicated in infants who are human immunodeficiency virus-1 (HIV-1) infected or are of unknown HIV-1 status

QUALIFYING STATEMENTS

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Aug

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society
Canadian Paediatric Society - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics

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Canadian Paediatric Society Infectious Diseases and Immunization Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Academy of Pediatrics \(AAP\) Policy Web site](#).

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 23, 2004. The information was verified by the guideline developer on November 3, 2004. This summary was updated on January 21, 2005, following the release of a public health advisory from the U.S. Food and Drug Administration regarding the use of nevirapine.

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